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10/057,197	10/26/2001	Martin J. Wensley	509032001500	1701

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Richard R. Eckman
Morrison & Foerster LLP
755 Page Mill Road
Palo Alto, CA 94304-1018

EXAMINER

EREZO, DARWIN P

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/057,197

Applicant(s)

WENSLEY ET AL.

Examiner

Darwin P. Erez

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-65 and 124-134 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 39-43, 48-53, 56, 57, 65 and 124-130 is/are allowed.
- 6) ☒ Claim(s) 1-10, 14, 16-28, 30, 36, 44-47, 54, 55, 58-64 and 131-134 is/are rejected.
- 7) ☒ Claim(s) 10-13, 15, 29, 31-35, 37 and 38 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claim 28 recites the limitation "the surface" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-5, 7-9, 14, 16, 18-28, 30, 36, 44-46, 54, 55, 59, 61-64 and 131-134 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,146,915 to Montgomery in view of US 5,894,841 to Voges.
6. As to claims 1, 18, 20, 30 and 54 Montgomery teaches a method for generating an aerosol comprising the steps of heating a physiologically active compound to vaporize at least a portion of said compound and mixing the resulting vapor with a

carrier gas (col. 2, lines 33-58) in a desired concentration (col. 2, lines 62-65); wherein the carrier gas is air (col. 1, line 9); wherein the compound is heated to a temperature for a period of time; wherein the compound is heated in a container (chamber) and passes to an orifice 4; and administering the aerosol to the patient.

Montgomery is silent with regards to the method comprising the step of mixing the vapor with the carrier gas in a ratio to form a desired particle size when a stable concentration of particles in the gas is reached.

Voges teaches that the droplet size of an aerosol delivered to a patient is a function of the carrier gas pressure and velocity (col. 1, lines 43-55).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Montgomery to include the step of mixing the resulting vapor with a carrier gas in a ratio to form a desired particle size since Voges teaches that it is well known in the art to control the particle size since the particle size is a function of the delivered pressure and velocity of the carrier gas, i.e., controlling the pressure and velocity of the carrier gas will alter the ratio of vapor to carrier gas. Furthermore, constant application of the same pressure and velocity of the carrier gas would produce aerosol with the same particle size, thus producing a stable concentration (inherent via the function of the pressure and velocity of the carrier gas in relation to the vapor).

7. As to Claims 2 and 5, the above combination teaches controlling the ratio of the vapor to gas by regulating the flow of said gas (pressure and velocity of the carrier gas).

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8. As to claims 3, 4, 7-9, the above combination is silent with regards to specifically controlling the ratio of vapor to gas via the rate of vaporization by controlling the energy transferred to the compound during the heating step. However, this would have been an obvious step to one of ordinary skill in the art at the time the invention was made since Montgomery teaches an adjustable heater (col. 3, lines 26-27), which would inherently regulate the rate of vaporization.

9. As to claim 14, the above combination teaches depositing the compound into a substrate (the vaporizing chamber **12** of Montgomery) prior to heating.

10. As to claims 16 and 46, the above combination teaches the particle size in the range of about 1-3 microns (col. 5, lines 3-4 of Voges).

11. As to claim 19, the above combination teaches a nicotine compound (col. 3, line 2 of Voges).

12. As to claims 21-22, the above combination discloses the claimed invention except for recited range of time. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to arrive at the recited range, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

13. As to claims 23 and 26, the above combination teaches the gas mixed at a closely controlled flow rate in order to maintain a stable concentration of particle size.

14. As to claim 24, Montgomery teaches preventing the increasing in gas temperature by mixing the carrier gas (col. 3, line 54 – col. 4, line 2).

15. As to claim 25, the above combination is silent with regards to the gas temperature increase no greater than 15°C but is inherent since Montgomery teaches a method that prevents the increase in gas temperature.

16. As to claim 27, the above combination teaches a laminar flow that is maintained across the surface of the compound in order to maintain a stable concentration of particle size.

17. As to claim 28, Fig. 2 of Montgomery shows a gas flow that is turbulent (venturi effect).

18. As to claim 36, the above combination discloses the claimed invention except for recited range of the surface area. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to arrive at the recited range, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

19. As to claim 44, Montgomery teaches the compound deposited into a thermally conductive substrate since chamber **12** includes heaters **32**.

20. As to claim 45, the above combination teaches the compound contained in heating-vaporization zone (vaporizing chamber **12**) and rapidly mixing the vapor with the carrier gas at a desired ratio as mentioned in the rejection of claim 1.

21. As to claim 55, the above combination teaches continuously introducing a compound into the vaporizing chamber since it is inherent that the vaporizing chamber is fully capable of being refilled.

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22. As to claim 59, Montgomery teaches a substrate (the vaporizing chamber **32**) having a plurality of sections that are heated (heaters **32**).

23. As to claims 61-64, Montgomery is silent with regards to the operation of the heaters. However, it would have been obvious to one of ordinary skill in the art to use any well known heaters, including inductive, thermal, dielectric or resistive heaters, since these heaters are well known in the art.

24. As to claims 131-134, it is well known in the art to use vaporizers to provide mist to a user's eye, skin or mucousa and would have been obvious to one of ordinary skill in the art.

25. Claims 6 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Montgomery in view of Voges, and in further view of US 4,484,576 to Albarda.

The above combination of Montgomery/Voges is silent with regards to an annunciating signal when the flow rate of the carrier gas is out of range. Albarda teaches a medical device having a flow of respiratory gas, wherein the flow of respiratory gas includes a warning lamp or annunciating signal (col. 4, line 25).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of the above combination to include the use of a warning lamp since it is beneficial to alert the user the user/patient if the device is malfunctioning or operating outside the normal parameters.

26. Claims 17 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Montgomery in view of Voges, and in further view of US 5,874,841 to Weers et al.

The above combination of Montgomery/Voges is silent with regards to the particle size in the range of 10 nm to 100 nm. Weers teaches that is known in the respiratory art to have particle sizes in the range of 10 nm to 100 nm (col. 5, line 6). Therefore, it would have been obvious to one of ordinary art at the time the invention was made to modify the steps taught by the above combination to include the particle size range of 10 to 100 nm since Weers teaches that the recited range is known in the art and would be dependent upon the intended therapy.

27. Claims 58 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Montgomery in view of Voges, and in further view of US 6,090,212 to Mahawili.

The above combination teaches all the limitations of the claim, as recited in the above rejections, but is silent with regards to a heater means comprising changing the focus of photon energy. Mahawili teaches a heater wherein the photon energy is used to provide heat. Therefore, it would have been obvious at the time the invention was made to use the heater of Mahawili in the method of Montgomery/Vogue, since it is well within the scope of one ordinary skill in the art to replace Montgomery's heater with any well known heater, including the heater of Mahawili.

Allowable Subject Matter

28. Claims 10-13, 15, 29, 31-35, 37 and 38 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
29. Claims 39-43, 48-53, 56, 57, 65 and 124-130 are allowed.

Response to Arguments

30. Applicant's arguments with respect to claims 1-10, 14, 16-28, 30, 36, 44-47, 54, 55, 58-64 and 131-134 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erez who's telephone number is (703) 605-0420. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott or Shaver can be reached on (703)308-0858. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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GLENN K. DAWSON
PRIMARY EXAMINER